AMENDMENTS TO THE SPECIFICATION

Please enter the following amendments to the specification. For the Examiner's convenience, the following amendments include markings to show the changes to a portion of the specification relative to the immediate prior version of that portion of the specification.

REPLACE Paragraph [0005] with the Following:

[0005] Using data describing contraindications and complications from FDA guidelines, public manufacturer data, clinical results from professional industry conferences, interdisciplinary scientific literature and negative case law, as well as dynamic data about surgeons' outcome and results history for the surgery, the method calculates in real time a customized risk assessment in terms of the probability of a successful outcome for the patient undergoing a surgery or treatment by a certain physician using a selected device ~~devices~~ or therapy. Based on the customized risk analysis, the method causes a consent form to be generated in real time, which comprises standardized and individualized paragraphs explaining the risks associated with the surgery or treatment for the patient.

REPLACE Paragraph [00016] with the Following:

[00016] Fig. 1 illustrates a prior art method for providing a patient an informed consent form. As shown, the prior process includes information on the absolute contraindications **10** of refractive laser surgery for correcting vision, which is gathered from the medical literature, FDA guidelines, the manufacturer's warnings and professional conferences. These absolute contraindications **10** have traditionally been used to formulate informed consent forms and to assess risks for patients considering the procedure at the point **100** when the surgery commences on the general public.

REPLACE Paragraph [00017] with the Following:

[00017] As Fig. 1 shows, once the "informed" consent is formulated, there is little or no opportunity in the prior art process to re-formulate the informed consent so as to include the mounting evidence **30** of complications resulting from the procedure. That is, the basis for the informed consent form in the prior art method constitutes almost entirely the absolute contraindications **10** originally formulated before actual practice of the surgical technique on the public.

REPLACE Paragraph [00019] with the Following:

[00019] Fig. 2 illustrates an exemplary embodiment of the present method in which the data is continually accumulated, processed, and presented to the patient to provide an up to the moment truly informed consent. A contracted health care provider **280**, such as a hospital, a clinic, physician's practice group or a sole practitioner contracts to become a participating member. Participation in the present process provides members and their patients the ability to calculate and print out an individualized risk assessment for undergoing surgery. Semi-static data **200**, which comprises information on absolute contraindications **210** and emerging contraindications **220**, emerging data relating to complications **230** occurring as a result of the surgery, and unknown contraindications **240** are input into the rule-based, informed consent engine **250**. The method then calculates, using a clinical basis process **260** (shown in more detail in Figure 3), a customized risk analysis for the patient contemplating a procedure.

REPLACE Paragraph [00021] with the Following:

[00021] Fig. 3 illustrates an embodiment of the clinical basis process **260** [[**300**]] in which Semi-static data **200** and Dynamic data **350** are used to generate the rule-based algorithm **390**, which shapes the customized Dynamic Informed Consent Form **270**. The algorithm **390**

formulates rules of risks relating to the surgical procedure **380** and rules of risks developed from analyzing data on post-operative events and outcomes **370**. In turn, the generated rules **370** and **380** do not remain static but are re-evaluated and re-generated upon the input of data **310** on patients' pre-operative care, data **340** on patients' [[and]] post-operative care [[**340**]], data **320** on the surgical procedure, and data **330** on the positive and negative outcomes of the surgery as performed by surgeons associated with the health care provider.

REPLACE Paragraph [00022] with the Following:

[00022] The clinical basis process **260** [[**300**]] is a real time, iterative calculation of the risks for an individual patient, considering not only the semi-static data **200** of contraindications but also the dynamic data **350** on complications and emerging contraindications, which relate to the outcome and result track record of particular surgeons associated with a contracted health care provider. In other words, the clinical basis process **260** [[**300**]] evaluates an individualized patient risk assessment from all the dynamic data on patient outcomes and results of surgeries performed by various surgeons of a contracted provider **280** as well as from the semi-static data **200** relating to surgical devices used for the procedure. The same process is equally adapted to the evaluation and risk assessment related to other medical therapeutic processes and treatments and those who provide them.

REPLACE Paragraph [00023] with the Following:

[00023] Once calculated, the risk assessment is presented in the form of a customized dynamic informed consent form **270**. This is accomplished by drafting separate sentences or paragraphs that explain different risks and creating a calculus that associates different explanatory sentences or paragraphs with different patient conditions and for different surgeons.

REPLACE Paragraph [00024] with the Following:

[00024] The method is iterative and dynamic in that the clinical basis process **260** [[**300**]] may be continually updated with real time data to provide a continually updated rule-based algorithm **390**. That is, as updated data on surgeons' and patients' outcomes and results history are acquired, the rule-based algorithm **390** both fine-tunes the surgical risks associated with various patient conditions and different surgeons and updates the calculus that associates the risk explanations with these conditions and surgeons. By updating the risk assessment algorithm and the calculus for associating explanations with surgery conditions particularly by inputting dynamic data **350**, the resultant informed consent form may be continually updated and customized for individual patients.

REPLACE Paragraph [00026] with the Following:

[00026] An algorithm-based data engine dynamically processes and analyzes static and dynamic data on a continuing, recursive basis. The result is a presentation in real-time that identifies risk in surgical and medical procedures that provides a patient with a live, state of the moment informed consent based on existing indications and warnings, literature, and iteratively processed data gathered from other patients. The process can also generate warnings based on all available data when such warnings would be appropriate.